Date of Approval Letter:

## FREEDOM OF INFORMATION SUMMARY

## SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

## NADA 008-804

TM-50, TM-SOD, TM-100, and TM-100D Type **A** Medicated Articles (oxytetracycline)

"to establish a zero-day pre-slaughter withdrawal period for cattle administered oxytetracycline at 10 mg/lb body weight per day for 14 days"

Sponsored by: Phibro Animal Health

## 1. GENERAL INFORMATION:

a. File Number: NADA 008-804

b. Sponsor: Phibro Animal Health

710 Route 46 East

Suite 401

Fairfield, New Jersey 07004

Drug Labeler Code: 066104

c. Established Name: Oxytetracycline quaternary salt equivalent to

oxytetracycline hydrochloride

d. Proprietary Names: TM-50, TM-SOD, TM-100, and TM-100D

e. Dosage Form: Type A Medicated Article

f. How Supplied: 50 lb (22.6 kg) bags

g. How Dispensed: OTC

h. Amount of Active Ingredients: TM-50 and TM-SOD: 50 g/lb; TM-100 and

TM-100D: 100 g/lb

i. Route of Administration: Oral, via feed

j. Species/Class: Chickens, turkeys, swine, cattle, sheep, lobsters,

honey bees (on "D" product labeling only)

k. Recommended Dosage and <u>Chickens</u>: Increased rate of weight gain and

Indications: improved feed efficiency – 10-50 g/ton, feed continuously. Control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl

cholera caused by Pasteurella multocida

susceptible to oxytetracycline – 100-200 g/ton, feed continuously for 7-14 days. Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and

Escherichia coli susceptible to oxytetracycline – 400 g/ton, feed continuously for 7-14 days.

Reduction of mortality due to air sacculitis (air sac infection) caused by *Escherichia coli* susceptible to oxytetracycline – 500 g/ton, feed continuously for

5 days.

<u>Turkeys</u>: For growing turkeys for increased rate of weight gain and improved feed efficiency – 10-50g/ton, feed continuously. Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline – 100 g/ton, feed continuously for 7-14 days. Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline – 200 g/ton, feed continuously for 7-14 days. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline – 25 mg/lb of body weight daily, feed continuously for 7-14 days.

Swine: Increased rate of weight gain and improved feed efficiency – 10-50 g/ton, feed continuously. Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline – 10 mg/lb of body weight daily, feed continuously for 7-14 days. For breeding swine for control and treatment of Leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline – 10 mg/lb of body weight daily, feed continuously for not more than 14 days.

Calves including Preruminating (Veal) Calves, Beef Cattle, and Non-Lactating Dairy Cattle: For calves (up to 250 lb) for increased rate of weight gain and improved feed efficiency – 0.05-0.1 mg/lb of body weight daily, feed continuously. For calves (250-400 lb) for increased rate of weight gain and improved feed efficiency – 25 mg/head/day, feed continuously. For growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses – 75 mg/head/day, feed continuously. For prevention and treatment of the early stages of shipping fever complex – 0.5 to 2.0 g/head/day, feed 3 to 5 days before and after

arrival in feedlots. Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline – 10 mg/lb of body weight daily, feed continuously for 7-14 days.

<u>Sheep</u>: Increased rate of weight gain and improved feed efficiency – 10-20 g/ton, feed continuously. Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline - 10 mg/lb of body weight daily, feed continuously for 7-14 days.

<u>Honey bees</u>: (TM-SOD and TM-100D only): Control of American foulbrood caused by *Bacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline – 200 mg/colony.

<u>Lobsters</u>: Control of gaffkemia in lobsters caused by *Aerococcus viridans* – 1 g/lb of medicated feed, feed for 5 days as the sole ration.

1. Pharmacological Category:

Antimicrobial

m. Effect of Supplement:

This supplement establishes a zero-day preslaughter withdrawal period for cattle administered oxytetracycline at 10 mg/lb/day for 14 days.

### 2. EFFECTIVENESS:

No further effectiveness data were required for the approval of this supplemental application.

## 3. ANIMAL SAFETY:

No further target animal safety data were required for the approval of this supplemental application.

### 4. HUMAN SAFETY:

## a. Toxicity:

No further basic toxicology studies were required for the approval of this supplemental application. However, CVM currently requires the sponsors to submit an assessment concerning the effects of antimicrobial residues present in the edible tissues of food animals on the intestinal flora of the consumer. The assessment submitted by the sponsor to comply with the human food safety requirements for antimicrobial drugs showed that the consumption of oxytetracycline residues present in edible tissues of cattle treated with  $10\,\mathrm{mg/lb/day}$  for  $14\,\mathrm{days}$  would not adversely affect the human intestinal flora, even when the complete meal basket is consumed in one day.

## b. Safe Concentrations of Total Residues:

As documented in the FOI Summary dated March 28, 1996, for NADA 113-232. The safe concentration for total tetracycline microbiological activity was limited to 1 ppm in the total diet (1.5 mg/person/day) (61 FR 67453), equal to an ADI of 25 micrograms per kilogram of body weight per day.

### C Tolerance for the Marker Residue:

Tolerances for oxytetracycline have been codified previously under 21 CFR 556.500 (61 FR 67453, December 23, 1996; 66 FR 46370, September 5,2001). Tolerances are established for the sum of residues of the tetracyclines in tissues of beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids as follows: 2 parts per million (ppm) in muscle, 6 ppm in liver, 12 ppm in fat and kidney, and 0.3 ppm in milk.

## d. Study Establishing the Withdrawal Period in Cattle:

Phibro Study Number USD 123-016

- 1. <u>Purpose</u>: A tissue residue study was conducted to quantify the concentration of oxytetracycline activity in edible tissues of cattle after oral administration, in feed, of oxytetracycline at a dose of 11 mg of oxytetracycline hydrochloride activity/lb of body weight (BW) for 14 days.
- 2. <u>Investigators</u>: Colorado Animal Research Enterprises (CARE), 6200 E. County Rd. 56, Fort Collins, CO 80524
- 3. Animals: six crossbred beef steers and six heifers
- 4. <u>Dosage form and dosage</u>: medicated feed at a dose of 11 mg oxytetracycline hydrochloride/lb BW/day for 14 consecutive days.

- 5. <u>Parameters measured and assay</u>: Oxytetracycline (parent) residues were measured in liver, kidney, muscle, and fat using the regulatory analytical (microbiological) method. LOQ for liver and kidney was 100 ppb; for muscle and fat the LOQ was 75 ppb (microassay).
- 6. <u>Results:</u> Oxytetracycline concentrations in the edible tissues of treated cattle are summarized in Table 6.1.

Table 6.1: Concentration of oxytetracycline (ppm) in the tissues of cattle treated with oxytetracycline medicated feed at a dose of 11 mg/lb/day and slaughtered at practical zero withdrawal.

Gender		Tis	sue	
	Kidney	Liver	Muscle	Fat
Heifers	1.818±0.439	0.671±0.175	0.181±0.057	ND*
Steers	1.312±0.704	0.796±0.211	0.197h0.09 1	ND
Overall	1.247±0.563	0.734±0.196	0.189±0.073	ND

<sup>\*</sup>Residues were not detected in fat.

These data were used to calculate the single point 99<sup>th</sup> percentile upper tolerance limit (with 95% confidence) for oxytetracycline residues at zero withdrawal for kidney, liver, and muscle. The upper tolerance limit values are summarized in Table 6.2.

Table 6.2: Calculated tissue-specific upper tolerance limits (ppm) for oxytetracycline residues in cattle treated with medicated feed at a dose of 11 mg/lb/day and slaughtered at practical zero withdrawal.

Gender		Tissue	
	Kidney	Liver	Muscle
Heifers	3.40	1.56	0.47
Steers	4.88	1.87	0.66
Overall	3.36	1.47	0.46

The calculated upper tolerance limit value for each tissue is significantly less than the tissue-specific tolerance codified under 21 CFR 556.500. Therefore, it is concluded that the use of the oxytetracycline Type A Medicated Articles in cattle to provide oxytetracycline at doses up to 10 mg/lb body weight/day qualifies for a zero withdrawal.

## e. Regulatory Method for Residues:

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778). The method

is as published by the Food and Drug Administration, "Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Method, Reports, and Protocols," revised October 1968, reprinted December 1974.

## f. Microbial Food Safety Assessment:

This NADA supplement establishes a zero-day pre-slaughter withdrawal period for cattle treated with 10 mg oxytetracycline/lb body weight per day for 14 days. Because this change to NADA 008-804 does not change the product indication, dose, duration, or other conditions of use beyond the change in withdrawal period, an evaluation of Microbial Food Safety was determined not to be necessary at this time for this supplemental approval to this approved product.

### **5. AGENCY CONCLUSIONS:**

The data submitted in support of this supplemental NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that TM-50, TM-100, TM-SOD, and TM-100D Type A Medicated Articles are safe at a zero-day pre-slaughter withdrawal period when these products are administered to cattle for 14 days at a level of 10 mg/lb body weight/day in feed.

The Center for Veterinary Medicine has concluded that, for this product, adequate directions of use by the layperson have been provided and the product will have over-the-counter (OTC) status. Label directions provide detailed instructions in plain language. The drug product is not a controlled substance. Thus, the NADA retains OTC status, and the labeling is adequate for the intended use.

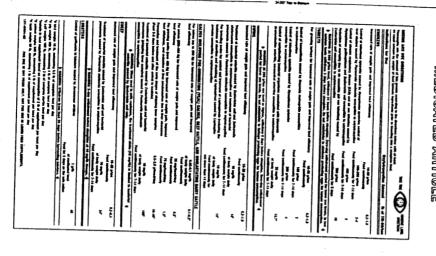
This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change required a reevaluation of certain safety data in the parent application.

### **6. ATTACHMENTS:**

Facsimile labeling is attached as indicated below:

- **A.** TM-50, TM-100, TM-SOD, and TM-100D Type A Medicated Articles
- B. Oxytetracycline Type B and C Blue Bird labels



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Type A Medicated Article

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Active Drug ingredient:
Oxytetracycline (from oxytetracycline quaternary sait)
equivalent to oxytetracycline hydrochloride

.... 50 g/I

101-8001-82 Distributed by

NADA #8-804, Approved by FDA

Phibro

Type A Medicated Article

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS TM-50 is a Philose Animel Health registered tradement for Dayletracycline RCI Philose Animel Health, Inn., Fairhead, NJ 97864 Net Weight 50 lb (22.6 kg)

STORE IN A DRY, COOL PLACE

# TM-50®

## TYPE A MEDICATED ARTICLE

Active <b>Drug</b> Ingredient:	
Oxytetracycline (from oxytetracycline quaternary salt)	
equivalent to oxytetracycline hydrochloride	50 g/lb

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert-for signs of allergic reactions — seek prompt medical treatment if such reactions are suspected.

## STORE IN A DRY, COOL PLACE

## SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS

TM-50 is a Phibro Animal Health registered trademark for Oxytetracycline HCI Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA

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Type A Medicated Article

**TM-50°D** 

Phibro

TM-50°D

type a Medicated article

IMISDIGATED ARTICE

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feets, including medicated premises, possess properties that may be a potential health hazard or a source of personal discoming to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

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NADA #8-804, Approved by FDA 7910000 191-9003-82 Net Weight 50 lb (22.6 kg)

STORE IN A DRY, COOL PLACE
SEE BACK PANEL FOR COMPLETE MIXING AND
USE DIRECTIONS AND WARNINGS

TH-66 is a Phibre Animal Realth registered tradomark for Oxylotrasystine KCI Phibre Animal Health, Inn., Feirfield, IIJ 67004

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TM-50°

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Phibro

101-0003-00

# TM-50®

## TYPE A MEDICATED ARTICLE

<b>Active</b>	Drug	Ingre	edie	nt:
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Oxytetracycline (from oxytetrac	cycline quaternary salt) equivalent to
oxytetracycline hydrochloride	

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, **possess** properties that may be a potential health hazard **or** a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

## STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS AND WARNINGS

TM-50 is a Phibro Animal Health registered trademark for Oxytetracycline HCI Phibro Animal Health, Inc., Fairfield, NJ 07004

## Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA 7919000 101-9003-02



Oxytetracycline Amount



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or growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abacesses	, 75 mg/head/day Feed continuously	15'
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HONEY BEES		
Control of American Foulbrood caused by Bactilius larvae, and European Foulbrood aused by Streptococcus pluton susceptible to asytetracycline	200 mg/colony	See Mixing Directions below
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control of gatikemia in lousters caused by Aerococcus wirldans	y 1g//b of medicated leed Feed for 5 days so the soleration	40
<b>▶</b> WARNING: Wilhdraw 1rom &	eed 30 days before harvesting lobsters. 4	
If bird weight 10 lb, consuming 0.5 lb of complete lead per day	*Include in feed supplement based on consumption of	
If pig weighs 100 lb, consuming 4 to all complets feed per day	"It animal weighs 600 lb, consuming 2 lb of supplemen	
If call weight 100 lb, consuming 2 lb of complete starter feed per day	"If lamb weighs 60 to, consuming 1 to of supplement p	er head per day
FOR USE IN DRY FEEDS ONLY. NOT FOR USE IN LIQUID FEED	SUPPLEMENTS.	
Mixing and Use Directions for Honey Lass Directions for Woney Lass Direction has high array concentration of this revolute an intermediate mixine must be pres Upper and mixwell. This mixture contains approximately 200 mg of oxytetracycline hydroc Usiling Directions. Apply 1 ox [200 mg oxytetracycline) of his mixture per colony. Apply the Using Directions. Use for (200 mg oxytetracycline) of his mixture per colony. Apply the Using Directions. Use for (200 mg oxytetracycline) of his mixture net his factorialism.	chloride activity per oz the dull on the outer parts or ends of the frames.	

Dusting Directions: Apply 101 (200 mg anytetracycline) of this mixture per oil by Parcolanty Apply the dull on the outer parts or ends of the frames.

Syrup Directions: Use 1 or (200 mg conytetracycline) of this mixture per oil by Parcolanty Ingles of the parcolanty Ingl

Crisco® is a trademark of Procter & Gamble, Cincinnati, OH 45202

Mixing and Use Elrections

Indications for Use  $\overline{\text{CHICKENS}}$ 

Throught or is the amount of this premis according to the directions below with at least an equal amount by weight or feed formula ingredients prior to blending into a complete feed.

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type a Medicated article

Type A Medicated Article

101-8002-02 Pishthulad by

Net Weight 50 lb (22.6 kg)

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS

STORE IN A DRY, COOL PLACE

type a Medicated article

Type A Medicated Article



## TYPE A MEDICATED ARTICLE

Active	Drug	Ingre	dient:
, ,,,,,,	-: 43		

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS

TM-100 is a Phibro Animal Health registered trademark for Oxytetracycline HCl Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA

101-9002-02

Distributed by

## M-100°

## TYPE A [MEDICATED ARTICLE

MIXIN( / N ) USE DIRECTIONS  Thorough 1	th at least	DIRECTION
	Outstance of the Aurora	
ndications for Use	Oxytetracycline L.mount	b of M-100
CHICKENS		
ncreased rate of weight gain and improved feed efficiency	19-50 g/ton Feed continuously	1.1-0.5
of of infectious y itle 1 y f); ; control of over the choice 3 caused by Pasteurella multocide susceptible to exytetracycline	100-200 g/ton Feed continuously lor 7-14 days	1-2
Control of chronic respiratory disease (CRD) and II sac Infection caused by ####################################	400 on 1 continuously for 7-14 days	4
leduction of mortality due to air sacculitis (air sac Infection) d by scherichia coll susceptible to 1 )	500 g Feed lyfor 5 day	5
At 5 gJ , withdraw 24 s briorr slaught 3 o in low calcium feeds withdraw 3 y c sia gh n. o not administ	y ithdra i riod fili ar a leve ler to chickens producing eggs for fiumar	
URKEY		
pr growing turkeys fi Incruased rate of ווּן ili and Improved d :i : אַ	-50 g/ton Feed li	00.5
int of itti caused y Hexamita meleagridis susceptible acyc. n	100 1 Feed continuous ly for 7 1 days	1 .
control of infectious synovitis caused by Mycoplasma synoviae usceptible to oxytetracycline	200 g/ton Feed continuously for 7-14 days	2
control of complicating bacterial organisms associated with biuecomb ransmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline	25 mgllb of body <b>weight</b> dally Feed continuously for <b>7-14</b> days	8 3'
WARNING At 200 g/ton use level or higher, withdraw 5 da period lor lower use levels. 00 not administer to turkeys p	ys briorr slaughter. Zero-day withdrawal roducing eggs for human consumption.	4
WINE		<del></del> :
creased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	01 0.5
reatment of bacterial enterills caused by Escherichia coll and Salmonella holerassuis susceptible to oxytetracycline and treatment of bacterial neumonia caused by Pasteurella multocida susceptible to oxytetracycline	10 mg/lb of body weight daily Faed continuously for 7-14days	. 1
or breeding swine for control and treatment of Leptospirosis (reducing the ncidence of abortion and shedding of leptospirae) caused by Leptospira omonasusceptible to oxytetracycline	10 mgllb of body weight dally Feed continuously for not more than 14 days	£ '
ALVES INCLUDING PRE-RUMINATING (VEAL) CALVES, BEEF CATTLE,	AND NONLACTATING DAIRY CATTLE	-
or calves (up to 250 lb) for increased rate of weight gain and Improved sed efficiency	0.05-0.1 mg/lb of body weight dally Feed continuously	0.0Ei- D.13
or calves (250-400b) for increasedrate of weight gain and improved sed efficiency	25 mg/head/day Feed continuously	0.254
or growing cattle (over 4001b) tor Increased rate of weight gain, improved sed efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day Feed continuously	0.7 (4
reventionand treatment of the rarly stages of shipping fever complex eed 3-5 days before and after arrival in feedlots)	0.5-2.0 g/head/day	5-214
reatment of bacterial enteritis caused by Escherichia coli and bacterial neumonia (shipping fever complex) caused by Pasteurelia multocida usceptible to oxyletracycline	10 mglib of body weight daily Feed continuously for 7-14 days	50
WARNING Whrn used in milk replacers, the	treatment claim (10 mg/lb) 🗻	
HEEP	oneroma con only,	
ncer  creasedrate of weight gain and improved feed efficiency	10-20g/ton	01-02
reatment, of bacterial <b>Entantis caused by Escherichia coll</b> and bacteric neumonia caused by <i>Pasteurella multocida</i> susceptible to oxytetracycline	Feed continuously  10 rg/lb  of body weight daily  Feed continuously for 7-14 days	124
▶ WARNING: 5-day withdrawal briorr slaugi	· · · · · · · · · · · · · · · · · · ·	
OPETERS	·	— (Mari
OBSTERS Ontrol of gaffkemia in lobsters caused by Aerococcus viridans	1g/lb of medicatedfeed	20
▶ WARNING Withdraw from feed 30 days be	Feed for 5 days as the role ration  fore harvesting lobsters. 4	
t bird welghs 101b, consuming 06 1b of complete feed per day  1 pig weighs 100 lb, consuming 4 lb of complete feed per day  1 calf weighs 100 lb, consuming 2 lb of complete starter leed per day  1 calf weighs 100 lb, consuming 2 lb of complete starter leed per day  1 calf weighs 500 lb, consuming 2 lb of supplement per head per day  1 lamb weighs 60 lb, consuming 1 lb of supplement per head per day  1 lamb weighs 60 lb, consuming 1 lb of supplement per head per day  1 1 lamb weighs 60 lb, consuming 1 lb of supplement per head per day  1 1 lamb weighs 60 lb, consuming 1 lb of supplement per head per day		

Phibro

STORE IN A DRY, COOL PLACE SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS AND WARNINGS

TM-100

TYPE A MEDICATED ARTICLE M-100°

JTION: For use in manufacturing medicated animal feeds only. .....100 g/lb

P.L.

NADA 20-804, Approved by FDA 7921000 101-8004-92

Net Weight 50 lb (22.6 kg)

TH-100 is a Philire Asimal Realth registered trademark for Oxylotrasyellos HCI Philire Asimal Health, Inc., Febrileid, RJ 07064

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# TM-100°D

## TYPE A MEDICATED ARTICLE

Active	Drug 1	lngred	ient	•
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CAUTION: For use in manufacturing medicated animal feeds only.

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## STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS AND WARNINGS

TM-100 is a Phibro Animal Health registered trademark for Oxytetracycline HCl Phibro Animal Health, Inc., Fairfield, NJ 07004

## Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA 7921000 101-9004-02





	Mixing	and	Use	DΙ	recl	lons
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ndications for Use	Oxylelracycline Amount	lb of TM-100D/ton
HICKEN S		
ncreased rate of weight pain and improved feed efficiency	10-50 g/ten Ford conlinuously	0.1-0 5
Control of intectious synovitis caused by Mycoplasma synovise; control of fowl cholera caused by Pasteurella mullocidas usceptible to exytetracycline	100-200 g/lon Feed continuously for 7-14 drys	1-2
Control of chronic respiratory disease (CRO) and air sacinfection caured by Mycopfasma gaiffsepticum rnd Escherichia collsusceptible to oxytetracycline	400 plion Feed continuously for 7-14 days	4
leduction of mortality due to air saccultis (air saccinection) caused by scherichia collausceptible to oxytetracycline	500 pllon Feed continuously for 5 drys	5
WARNING: AI 500 g/lon level, wilhdraw 24 hours briorr slau In low calcium feeds wilhdraw 3 days before slaughter. Der	ghter. Zero-day wiihdrawai period for lower use levels. I administer to chickens producing agge for human cos	isumplien.
TURKEYS		
or growing lurkeys for increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed conlinuously	0.1-0.5
onited of hexamitlasis caused by Hexamita meleagridis ausceptible to exytetracycline	100 g/ton Fred conlinuously for 7-14 days	1
ontrol of infectious synovills caused by Mycoplasma synoviae susceptible to exytetracycline	200 pilon Feed continuously for 7-14 days	2
Antrol of complicating bacierial organisms associated with bluecomb ransmissible entertits, coronaviral enteritis) susceptible to oxyletracycline	26 mgllb of body weighl daily Feed conlinuourly for 7-14 days	8 2,
■ WARNING: Al 200 g/ten use leve) or higher, wi	hdraw 5 days before slaughter Zero-day withdrawal d	
SWINE		
ncressed rate of weight gain and Improved loads!!lolancy	10-50 pilon Fact conlinuously	g 1-0 5
realment of hacterial entertits paused by Escherichia con Jod Salmonelia choleraesula usceptible to oxytetracycline and treatment of bacterial pneumonta caused by systemelia multinicid susceptible to oxytetracycline	10 mg/lb of body weight dally Feed continuously for 7-14 days	5'
For breeding swine for control and treatment of Leptospirosis (reducing the incidence of abortion and shooding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to oxyletracycline	10 mg/lb of body weight dally Ford conlinuously for not more than 14 days	5'
CALVES including pre-ruminating (veal) calves, BEEF CATTLE, AND N	NLACTATING DAIRY CATTLE	
or calvas (up to 250 lb) for increased rate of weight gain and improved lead efficiency	0.05-0.1 mg/lb of body weight daily Fred conlinuourly	0.05-0.1
for calves (250-400 lb) for increased rate of weight pain and improved lead efficiency	25 mg/head/day Fred conlinuourly	0.25
or growing callis (over 400 lb) for increased rate of weight pain, improved fired efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day Feed continuously	0.75
revention and freatment of the early stages of shipping lever complex red 35-days before and after errival in feedlots)	0.5-2.0 g/head/day	5-20'
ealment of bacter(a) entertils caused by <i>Escherichta</i> coll and bacter(a) pneumon(a hipping lever complex) caused by Pasteure((a multocida susceptible io oxytetracycline	10 mg/lb of body weight dally Feed continuously far I-14 days	50°
WARNING When used in milk replacers, the entertile caused by Escherichia call only.	treatment claim (10 mgllb) is ilmited to bacterial	
HEEP		
acreased rate of weight pain and improved feed afficiency	10-20 pilon Fend continuously	0.1-0.2
realment of bacterial entertits caused by <i>Escharichia coll</i> and bacterial pncumonia aused by <i>Fasteurella mullogida</i> susceptible to oxytetracycline	10 mgllb of body weight dally Feed conlinuously for 7-14 days	12'
► WARNIIIG: 5-day wilhdrawai	hefore slaughter Ji 10 mgllb dosage. 🦸	
ONEY BEES		
ntrol of American Foulbrood caused by Sectifus larvas, and European Foulbrood caused by (replococcus plutan susceptible to explairacycline	200 mg/celony	See Mixing Directions below
WARHING: Remove at least	6 weeks prior to main honey flow.	
LOBSTERS		
Control of gaffkemia in lobaters caused by Aerococcus viridans	1 g/lb of medicated feed Feed for 5 days as the sole ration	20
WARNING: Withdraw from fee	d 30 days before harvesting lobsters. 🤙	
(I bird weighs 10 tb, consuming 0.8 th of complete feed per day If pig weighs 100 th, consuming 4 tb of complete feed per bay	findlude in Ired supplement based on consumption of all findings weights 500 lb, consuming 2 lb of supplement	

'il pig weighs 100 lb, consuming 4 lb of complete lead per bay
'il call weighs 100 lb, consuming 2 lb of complete starter (eed per day

\*If animal weighs 500 lb, consuming 2 lb of supplement per head per dry
\*If lamb weighs 60 lb, consuming 5 lb of supplement per head per day

FOR USE IN DRY FEEDS ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

Nising rind Use Directions for Honey Beas

Out in the high drug concentration of this product, an intermediate mixture must be prepared for use with bees. To prepare this intermediate mixture add 7 to of TM-1000 to 200 to of powdered sugar and mix well. This mixture contains approximately 200 mp of explainary 200 mp or exp

Extender Patty Directions: Use 4 or (800 mg oxyletracycline) of Ihlis mixture mixed with 165 g of vegetable shortening (Crisco® or equivalent) and 330 g of sugar. The patties are placed on the top bars of the brood nest frames

WARNING: this mixture should be fed in the spring or fail and consumed by the bees before main honey thow begins to avoid contamination of production honey. Honey stored during medication periods in combs for surplus honey should be removed following final medication of the bee colony and multinat be used for human food. Honey from bee colonies likely to be infected with fourbrood should not be used for preparation of medicated syrup supplements since it may be contaminated with sports of fourbrood and may assist in spreading the disease control lates it weeks before main honey flow, to not use in mannance rary to state applications. The state has specific regulations relative to disease control and medications. Contact the appropriate official or state departments of agriculture for specific infer- and intrastate laws and regulations.

Crisco® is a trademark of Propter & Gamble. Cincinna(i, OH 45202

## **OXYTETRACYCLINE** TYPE B **BAG** OR BULK

**BLUE BIRD CATTLE FEED MEDICATED** 

## ACTIVE DRUG INGREDIENT

20 g/lb

Oxytetracycline .....

INDICATIONS FOR USE	OXYTETRACYCLINE AMOUNT	lb of Type B/ton of Feed		
For calves (up to 250 lb) for increased rate of weight gain <b>and</b> improved feed efficiency	0.05-0.1 mg/lb of body weight daily Feed continuously	0.25-0.5'		
For calves (250-400 lb) for increased rate of weight gain and improved feed efficiency	25 mg/head/day Feed continuously	1.25 <sup>2</sup>		
For growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day Feed continuously	3.75 <sup>2</sup>		
Prevention and treatment of the early stages of shipping fever complex	0.5-2.0 g/head/day Feed 3-5 days before and after arrival in feed lots	25-100 <sup>2</sup>		
Treatment of bacterial enteritis caused by <i>Escherichia</i> coli and bacterial pneumonia (shipping fever complex)	10 mg/lb of body weight daily Feed continuously for 7-14 days	250 <sup>3</sup>		

## **GUARANTEED ANALYSIS**

Crude Protein (Min)	$\mathbf{Y}_{o}$
Equivalent crude protein from Non-Protein Nitrogen (NPN) when added (max)	%
Crude Fat (Min).	<b>Y</b> ⊙
Crude Fiber (Max)	$\phantom{aaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa$
Calcium (Min)	
Calcium (Max)	<del></del> %
Phosphorus(Min)	<del></del> %
Salt (Min)	$\mathbf{Y}_{o}$
Salt (Max)	$\mathbf{Y}_{o}$
	ppm
Potassium (Min)	%
Vitamin A (Min)	—пт

caused by Pasteurella multocida susceptible to

oxytetracycline

### **INGREDIENTS**

Ingredients as defined by AAFCO

WARNING: WHEN USED IN MILK REPLACERS, THE TREATMENT CLAIM (10 MG/LB) IS LIMITED TO BACTERIAL ENTERITIS CAUSED BY ESCHERICHIA COLI ONLY.

\_\_\_\_lbsk g ) **NET** WEIGHT

BLUE BIRD FEED MILL Robin, IN 00000

## OXYTETRACYCLINE TYPE C BAG OR BULK

**BLUE BIRD CATTLE FEED MEDICATED** 

## ACTIVE DRUG INGREDIENT

INDICATIONS FOR USE	OXYTETRACYCLINE AMOUNT		
For calves (up to 250 lb) for increased rate of weight gain and improved feed efficiency	0.05-0.1 mg/lb of body weight daily' Feed continuously		
For calves (250-400 lb) for increased rate of weight gain and improved feed efficiency	<b>25</b> mg/head/day <sup>2</sup> Feed continuously		
For growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day <sup>3</sup> Feed continuously		
Prevention and treatment of the early stages of shipping fever complex	0.5-2.0 g/head/day <sup>4</sup> Feed 3-5 days before and after arrival in feed lots		
Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia (shipping fever complex) caused	10 mg/lb of body weight daily <sup>5</sup> Feed continuously for 7- <b>14</b> days		

by *Pasteurella multocida* susceptible to osytetracycline

If a calf weighs 100 lb, consuming 2 lb of complete starter feed per day containing 5-10 g/ton oxytetracycline. Include in feed supplement containing 25 g/ton oxytetracycline based on consumption of 2 lb of supplement per head

per day

3If a calf weighs 500 lb, consuming 2 lb supplement per head per day containing 75 g/ton oxytetracycline.

## **GUARANTEED ANALYSIS**

Crude Protein(Min)	$oldsymbol{Y}_{\mathcal{O}}$
Equivalent crude protein from Non-Protein Nitrogen (NPN) when added (max)	$$ $\mathbf{Y}_{\mathcal{O}}$
Crude Fat (Min)	$$ $oldsymbol{Y}_{\mathcal{O}}$
Crude Fiber (Max)	
Calcium(Min)	<del></del> %
	$\mathbf{Y}_{o}$
Phosphorus (Min)	
Salt (Min)	YO.
Salt(Max)	<u></u> %
Selenium (Min)	ppm
Potassium (Min)	%
Vitamin A (Min)	ŢŪ

## **INGREDIENTS**

Ingredients as defined by AAFCO

WARNING: WHEN USED IN MILK REPLACERS, THE TREATMENT CLAIM (10 MG/LB) IS LIMITED TO BACTERIAL ENTERITIS CAUSED BY  $\it ESCHERICHIA\ COLI$  ONLY.

\_lbs (\_\_\_\_kg) NET WEIGHT

BLUE BIRD FEED MILL Robin, IN 00000

<sup>&</sup>lt;sup>4</sup>Include in a supplement based on consumption of 2 lbs of supplement per head per day containing 500-2000 g/ton oxytetracycline. SIf a calf weighs 500 lbs, consuming 2 lbs of supplement **per** head day containing 5000 g/ton oxytetracycline